DEPARTMENT OF HEALTH & HUMAN SERVICES

NOV 9 1999

Food and Drug Administration
Rockville MD 20857

3746 '99 NOV 10 P3:19

Beverly J. Warns
2503 Country Estates Drive
Madison, SD 57042-9740

Re: Docket No. 99P-4581/CP1

Dear Ms. Warns:

This letter responds to your petition dated October 18, 1999, which requests that we add liothyronine sodium to the list of bulk drug substances that may be used in pharmacy compounding under the provisions of section 503A of the Federal Food, Drug, and Cosmetic Act. For the reasons set out below your petition is denied. Although we are denying your petition, the denial will NOT stop you from continuing to receive the medication you are currently receiving.

Liothyronine sodium is the subject of a United States Pharmacopeia (USP) monograph and is also a component of drug products approved by the FDA. Section 503A allows compounding pharmacists and physicians to compound using bulk drug substances that are the subject of a USP monograph or are components of drug products that have been approved by the FDA. Since pharmacists and physicians are already allowed to compound with liothyronine sodium, there is no need to add the drug to the list of drugs that are not the subject of a USP monograph or that are not components of FDA-approved drug products, but that we still believe are suitable for compounding. We have called your pharmacist, whose phone number you were kind enough to give us, and he informed us that liothyronine sodium is the active ingredient in the "T3" drug product you are receiving. Therefore, we can be certain that our denial of your petition will not affect the availability of your medicine.

If you have any questions about this matter, please feel free to call Wayne Mitchell of our Center for Drug Evaluation and Research at 301-594-2041.

Sincerely yours,

for Dennis E. Baker
Associate Commissioner
for Regulatory Affairs

99P-4581

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